REMARKS

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, Claims 35-43 will remain pending in the application. Applicants have added Claim 43 and have amended Claims 35, 38-39 and 41-42. These changes do not introduce new matter, and their entry is respectfully requested.

In the Office Action of February 24, 2003, the Examiner set forth a number of grounds for rejection. These grounds are addressed individually and in detail below.

Rejections Under 35 U.S.C. § 102

Claims 35-42 stand rejected under 35 U.S.C. §102 (b) as being anticipated by Dranoff, et al (US Patent No. 6,637,483) for the reasons set forth on pages 2-3 of the Office Action. Claims 35-42 further stand rejected under 35 U.S.C. §102 (e) as being anticipated by Hiserdodt, et al., (WO 98/04282, 1998) for the reasons set forth on page 3 of the Office Action.

Applicants have amended independent Claim 35 and dependent Claims 38-39 and 41-42. Accordingly, Applicants respectfully traverse the rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. Verdegaal Bros. v. Union Oil Co. Of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. Scripps Clinic Research & Foundation v. Genentech Inc., 18 USPQ2d 1001, 1010 (Fed. Cir. 1991).

Independent Claim 35 of the present invention is directed to a novel composition for generating an immune response to a prostate tumor-associated antigen that stimulates a humoral response when provided on a proliferation-incompetent cell in the presence of GM-CSF and does not stimulate a humoral response when provided in the absence of GM-CSF. The prostate tumor-associated antigen has a molecular weight of 250 kD, 160 kD, 150 kD, 31 kD, 26 kD or 14 kD, as determined by SDS-PAGE, and does not cross-react immunologically with prostate-specific antigen.

The claimed prostate tumor antigens, under normal circumstances, do not elicit a humoral response as indicated in the Figures by the lack of detected immune response (a band on a Western blot) where the antibody source is either normal serum or serum taken from a patient prior to administration of the prostate tumor-associated antigen and a GVAX vaccine, which provides GM-CSF. However, when the prostate tumor-associated antigen is administered with GM-CSF, provided by the GVAX vaccine, the data shows that a humoral response by the patient to prostate tumor antigens of particular molecular weights was detected via Western blot, as indicated in Figures 4 to 7 of the present specification.

The present claims are not anticipated by Dranoff which fails to describe prostate tumor-associated antigens having the claimed molecular weight and immunological characteristics (i.e., stimulate a humoral response when provided on a proliferation-incompetent cell in the presence of GM-CSF and does not stimulate a humoral response when provided in the absence of GM-CSF). Accordingly, Dranoff does not teach each and every element as set forth in claim 35 of the present invention.

The office Action alleges that the burden is on the applicants to prove that the claimed composition is different from those taught by the prior art and to establish patentable differences. In this regard, Applicants respectfully submit that the claimed invention clearly contains

characteristics not disclosed in Dranoff. The Examiner has the burden to show that a characteristic not disclosed in the reference is inherent. In Continental Can Co. USA v. Monsanto Co., the Federal Circuit held "[T]o serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268, 20n USPQ2d 1746, 1749 (Fed. Cir. 1991). The Examiner has not provided any evidence that the elements of the claims are disclosed in the reference (i.e., the molecular weight and immunological characteristics of the prostate tumor-associated antigen). Therefore, the present invention is not anticipated by Dranoff.

With respect to the Hiserdodt reference, the Examiner alleges that "various compositions of the prior art comprising proliferation-incompetent cell tumor cell vaccine engineered to express GM-CSF inherently have the nucleic acids encoding antigens with sized ranging from 250 kD to 14 kD that do not react with PSA." Applicants respectfully disagree. The instant invention provides antigens of specific molecular weights, i.e., 250 kD, 160 kD, 150 kD, 31 kD, 26 kD and 14 kD. Hiserdodt does not disclose any antigen having the claimed molecular weight. Accordingly, Hiserdodt does not anticipate the instant invention.

Thus, the grounds for this rejection have been obviated and withdrawal of the 35 U.S.C. 102 rejection is respectfully requested.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 35-42 stand rejected under 35 U.S.C. §112, first paragraph, for lack of written description support in the originally filed specification for reasons set forth on pages 3 and 4 of

the Office Action. The Examiner alleges that the specification only supports the mixture of protein and the specification does not teach the isolation of and assaying of tumor-associated antigens consisting of any of the recited molecules.

Applicants respectfully traverse the rejection. The present claims find support in the specification as set forth below.

The claims recite particular prostate tumor antigens. The figures of the instant application depict Western blots wherein specific antisera bind to prostate tumor antigens that were not detectable prior to exposure of the host to proliferation-incompetent prostate tumor cells and GM-CSF. The current claims are supported by the description at least on page 7, lines 19-27; page 9, lines 12-19 (proliferation-incompetent); page 9, lines 26-27 (GM-CSF); page 10, lines 14-15 (autologous); page 10, lines 18-19 (allogeneic); and page 10, lines 32-34 (prostate cancer). More specifically, the figures show identification of prostate tumor associated antigens with a molecular weight of 250 kD (Figs. 5 to 7), 160 kD (Figs. 5 to 7), 150 kD (Figs. 2 to 4), 31 kD (Fig. 2), 26 kD (Fig. 2) or 14 kD (Figs. 5 to 7) The control antisera were obtained from the same patients prior to exposure to the GM-CSF and vaccine, and specific antibody did not exist at that time. Based on a review of the specification, one of skill in the art would well recognize that the inventors were in possession of the claimed invention at the time the application was filed.

It is believed that this ground of rejection has been obviated, and therefore, the rejection under 35 U.S.C. 112 first paragraph should be withdrawn.

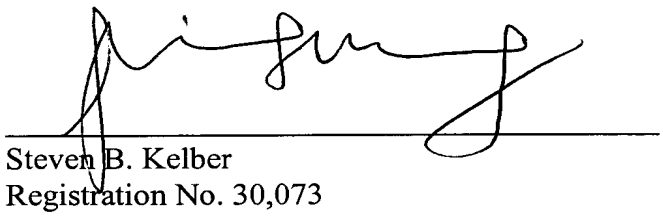
CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to contact Ping Wang, M.D. (Reg. No. 48,328) at the telephone number listed below.

Respectfully submitted,

PIPER RUDNICK LLP



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